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ATMS 2006-434

Jan 18, 2006

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

## NOTIFICATION OF STATEMENT OF NUTRITIONAL SUPPORT

Dear Sir or Madam:

In accordance with Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, and pursuant to 21 C.F.R. § 101.93, we hereby provide the following notice with regard to the marketing of the Dietary Supplement described below:

Distributor: Iovate Health Sciences U.S.A. Inc., 3880 Jeffrey Blvd., Blasdell, NY 14219

Name of Supplement: LEUKIC<sup>TM</sup> Statement of Nutritional Support:

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- 1. WORLD'S FIRST 100% ANABOLIC COMPOUND
- 2. ZERO NEGATIVE ANDROGENIC SIDE EFFECTS
- 3. PRODUCES PERMANENT GAINS IN HIGH-QUALITY DENSE MUSCLE
- 4. IMMEDIATELY STIMULATES MUSCLE GROWTH
- 5. ADVANCED ANABOLIC ACTIVATOR
- 6. Team MuscleTech™ researchers have been working tirelessly for over 10 years in search of the world's first 100% pure anabolic formula. A formula so powerful that in just one serving it could bypass the hormone/receptor anabolic mechanism and trigger muscle anabolism all on its own. A formula so potent it could stop muscle catabolism and protein breakdown in its tracks. That formula has arrived. It's called LEUKIC™, and it's redefining the way you build muscle and increase strength and performance.
- 7. Hormones are involved in building muscle when they bind to receptors. The receptors then send a signal to the inside of the muscle fibers, telling them to grow. However, when you elevate one hormone, you cause others to increase or decrease, creating a hormonal mix that may work for a day but set your body back by weeks and even months through what scientists call the "negative feedback loop mechanism." Team MuscleTech<sup>TM</sup> researchers, however, have bypassed this hormonal loop. (With ongoing weight training) by activating the enzymatic complex responsible for transmitting the body's most powerful anabolic signal without elevating or decreasing hormonal levels, LEUKIC achieves what no other product can 100% pure anabolism for hard, dense, permanent muscle growth.
- 8. LEUKIC activates the anabolic signals that hormones normally activate, without actually manipulating hormones themselves. This makes LEUKIC the most effective, powerful, and purely anabolic compound in existence. With one serving, you can immediately turn on the anabolic musclebuilding process and turn off catabolism. And you can do it any time you

- want, because LEUKIC works all the time, every time. \*\*This leads to gains in permanent, high-quality, dense muscle growth without any negative androgenic side effects no water retention, no bloating, no receptor downgrade, and no temporary gains.
- 9. According to a clinical study published in the prestigious, American Journal of Physiology, Endocrinology and Metabolism, infusion of the key component of LEUKIC is associated with increased phosphorylation in skeletal muscle from human subjects at rest. In another journal, Clinical Nutrition and Metabolic Care, one researcher noted the unique ability of the key component of LEUKIC to stimulate protein synthesis in skeletal muscle. This groundbreaking study confirms the anabolic power of LEUKIC. The key component in LEUKIC functions outside of the hormone/receptor mechanism as an anabolic signal molecule that regulates protein synthesis (muscle growth). Nothing else can do what LEUKIC does to create an anabolic environment in the muscle.

To the best of my knowledge, the information contained in this notice is complete and accurate, and lovate Health Sciences USA Inc. has substantiation that the statements are truthful and not misleading.

Sincerely,

Shan Chaudhuri

Regulatory Affairs Manager